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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/277,401	03/26/1999	MICHAEL JAYE	22,944-C USA	3515

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/12/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/277,401

Applicant(s)

JAYE ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,71,74-76,78-91 and 95 is/are rejected.
- 7) ☒ Claim(s) 96 and 97 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>18</u> . | 6) <input type="checkbox"/> Other: |

Continuation of Disposition of Claims: Claims pending in the application are 1,7,8,10,11,13-16,19-23,40,41,43-47,49-53,55-59,63-65,71,73-76,78-91 and 93-97.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1,7,8,10,11,13-16,19,21-23,40,41,43-47,49-53,55-59,63-65,73,93 and 94.



PONNATHU ACHUTHA MURTHY
SUPERVISORY PATENT EXAMINER
TECHNICAL STAFF (P) (CLASS 3500)

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (Paper No. 15, mailed on May 7, 2002), Applicants filed an amendment and response received on November 14, 2002 (Paper No. 17). Said amendment cancelled Claims 66-70, 72, 77, and 92, amended Claims 20, 85, 90, and 91, and added new Claims 96-97. Thus, Claims 1, 7, 8, 10, 11, 13-16, 19-23, 40, 41, 43-47, 49-53, 55-59, 63-65, 71, 73, 74-76, 78-91, and 93-97 are pending in the instant Office action.

Election

2. This application contains Claims 1, 7, 8, 10, 11, 13-16, 19, 21-23, 40-41, 43-47, 49-53, 55-59, 63-65, 73, 93, and 94 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 C.F.R. § 1.144) See M.P.E.P. § 821.01.

Claims 1, 7, 8, 10, 11, 13-16, 19-23, 40, 41, 43-47, 49-53, 55-59, 63-65, 71, 73, 74-76, 78-91, and 93-97 are pending. Claims 1, 7, 8, 10, 11, 13-16, 19, 21-23, 40-41, 43-47, 49-53, 55-59, 63-65, 73, 93, and 94 are withdrawn from further consideration as non-elected inventions. Thus, Claims 20, 71, 74-76, 78-91, and 95-97 will be examined herein.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/032,254 and 60/032,783 filed on December 6, 1996 and U.S. non-Provisional Application No. 08/985,492 filed on December 5, 1997.

Information Disclosure Statement

4. The information disclosure statement filed on December 23, 2002 (Paper No. 18) has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Drawings

5. The drawings are considered informal for the reasons detailed in the copy of PTO Form 948 attached to Paper No. 15. Appropriate correction is required in response to the instant Office action and may not be held in abeyance (see 37 C.F.R. § 1.85(a)).

Compliance with the Sequence Rules

6. By virtue of Applicants' amendment to the specification describing all sequences by SEQ ID NOs, the instant application now fully complies with the sequence rules.

Withdrawn - Objections to the Specification

7. Previous objection to the specification for the abbreviations EL, LPL, HL, and PL is withdrawn by virtue of Applicants' amendment.

8. Previous objection to the specification for being confusing in its description of Figure 14 on page 96, lines 24-27, is withdrawn by virtue of Applicants' amendment.

Maintained - Objections to the Specification

9. Previous objection to the specification for being confusing about the origin of the LIPG protein sequences is maintained. Applicants have not addressed this issue by amendment or argument. The following is repeated from the previous Office action for clarity:

“Particularly, it is difficult to discern which SEQ ID NOs related to human and rabbit sequences. Clear identification of SEQ ID NOs and origin of the polypeptides, preferably in the figures, is required. Moreover, the relationship between SEQ ID NOs: 6, 8, and 10 is not clear. An added sentence to the specification concerning SEQ ID NO:8 as the full-length, 500 residue sequence and SEQ ID NO:6 being a fragment of residues 1-354 and SEQ ID NO:10 being a fragment of residues 1-345 would be helpful in enhancing the clarity of the specification.”

10. Previous objection to the Abstract for not completely describing the disclosed subject matter is maintained. Applicants have not effectively addressed this issue by amendment or argument. The following is repeated from the previous Office action for clarity:

“It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the source species of LIPG polypeptide, human and rabbit, for completeness.”

Withdrawn - Claim Objections

11. Previous objection to Claims 20, 66-71, 77-85, 87, 92, and 95 for containing non-elected subject matter is withdrawn by virtue of Applicants' amendment and/or cancellation of the instant claims.

12. Previous objection to Claims 69, 70, and 92 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claims.

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13. Previous objection to Claim 72 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claim.

Maintained – Claim Objections

14. Previous objection to Claim 95 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that the limitation of being "antigenic" further limits the subject matter of Claim 85. While it is true that this aspect further limits the subject matter of Claim 85, the removal of the limitation of the full-length protein, as previously noted, broadens the claim. The Examiner suggests rewriting Claim 95 in independent form.

Withdrawn – Claim Rejections 35 U.S.C. § 112, second paragraph

15. Previous rejection of Claims 66-70, 72, 77, and 89-91 under 35 U.S.C. § 112, second paragraph for the abbreviation "LIPG" is withdrawn by virtue of Applicants' cancellation of said claims and/or the Examiner's reconsideration. Each of Claims 89-91 corrects the deficit of the parent claim with respect to the confusing phrase because they each define the amino acid sequence claimed.

16. Previous rejection of Claims 66-68 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrases "enhancing the enzymatic activity" or "enhances the enzymatic reaction" is withdrawn by virtue of Applicants' cancellation of said claims.

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17. Previous rejection of Claims 67-68 under 35 U.S.C. § 112, second paragraph, as being indefinite for the abbreviation “apo” is withdrawn by virtue of Applicants’ cancellation of said claims.

18. Previous rejection of Claims 85-92 and 95 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “**the** LIPG gene” (emphasis added) is withdrawn by virtue of Applicants’ amendment to said claims removing the phrase.

19. Previous rejection of Claims 89-91 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “a 39 kD catalytic domain of the triacylglycerol lipase family” is withdrawn by virtue of the Examiner’s reconsideration. Each of Claims 89-91 corrects the deficit of the parent claim with respect to the confusing phrase because they each define the amino acid sequence claimed.

Maintained – Claim Rejections 35 U.S.C. § 112, second paragraph

20. Previous rejection of Claims 20, 71, 74-76, 78-88, and 95 under 35 U.S.C. § 112, second paragraph for the abbreviation “LIPG” is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive.

Applicants argue that the term “LIPG polypeptide” is a technical term clear to those skilled in the art referring to an endothelial lipase. If this is the case, the Examiner suggests replacing “LIPG polypeptide” with ---endothelial lipase (LIPG) polypeptide--- for clarity. Applicants also argue that the definition recited in Claims 20 and 85, as amended, clarify the metes and bounds of the claim. This is not the case. The following terms in the amended Claims

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20 and 85 render the claims unclear as to their metes and bounds: “homology” – it is unclear what level or relatedness constitutes homology; “position” – it is unclear to what sequence this position number is in reference; “a 19-residue lid region which is characteristic of LIPG polypeptide” – must this be an exact 19-mer sequence? if so, if there a SEQ ID NO? must there be only relatedness to said lid region? For all these reasons, the instant claims are unclear as to their metes and bounds.

21. Previous rejection of Claims 85, 87, 88 and 95 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “a 39 kD catalytic domain of the triacylglycerol lipase family” is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive. Moreover, Claims 20, 71, 74-76, and 78-84 are rejected below for these same reasons due to their amendment to include this rejected phrase.

Applicants argue that an example of the domain, SEQ ID NO:10, in the specification adequately describes this term. This is not the case. As Applicants note, the definition on the specification also includes analogues, derivatives, or mutants that retain at least one biological property of SEQ ID NO:10. It is wholly unclear what kind of structure this encompasses since the variability of the structure is boundless and no clear definition of biological activity is noted. For all these reasons, the phrase is considered unclear.

22. Previous rejection of Claims 90 and 91 under 35 U.S.C. § 112, second paragraph, as being unclear as to how a polypeptide having the same amino acid sequence (SEQ ID NO:8) can produce different bands (68 kD and 55 kD) on a 10% SDS-PAGE gel is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive. Applicants argue that the

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68kD polypeptide is likely a form of the 55 kD polypeptide. The Examiner fails to see how this clarifies the question. As previously noted, if the smaller apparent molecular protein (Claim 90) is a truncated version, then its sequence is not SEQ ID NO:8. If the smaller protein is not truncated, then the different MW's are wholly unclear. Claims 90 and 91 appear to be drawn to the same subject matter – that is SEQ ID NO:8. Appropriate clarification is required.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, first paragraph

23. Previous rejection of Claims 66-70, 72, 77, and 92 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation of said claims.

24. Previous rejection of Claims 66-68 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation of said claims.

25. Previous rejection of Claim 92 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation of said claim.

Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

26. Previous rejection of Claims 20, 71, 78-85, 88, and 95 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that the amendment to Claims 20 and 85 have included the requisite structural and functional limitations necessary to obviate the instant rejection. This is not the case because the structural limitations are not clear

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as noted above in a rejection under 35 U.S.C. § 112, second paragraph. Without clear structural limitations, the instant rejection is maintained.

As previously noted,

“The instant specification describes a single species of the claimed (and elected) genus, that is human SEQ ID NO:8 – the full-length protein. SEQ ID NOs: 6 and 10 are only truncations of the same sequence. No identification of common characteristics is claimed. Particularly, no definite structure, such as relatedness to SEQ ID NO:8, is listed as a claim limitation. No enzymatic function is listed as a claim limitation. Thus, one of skill in the art would be able to predict other members of the genus based on the disclosure. The Examiner suggests the inclusion of definite structural (relatedness to SEQ ID NO:8) and functional (having lipase activity) in the claims.”

27. Previous rejection of Claims 74-76 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that the structure of the parent claim, Claim 20, is sufficient to describe not only the parent claim, but also the broad term “variant” in the instant claims. Not only is the structure in Claim 20 insufficient (see maintained rejection above), but also, the term “variant” of SEQ ID NOs: 6, 8, or 10 imparts no structural limitation as well. For these reasons, the instant rejection is maintained.

28. Previous rejection of Claim 87 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants' argue that Claim 85 has a definite structure. As noted above, this is not the case. Thus, Claim 87 is limited by a defined function, but no defined structure.

Withdrawn – Claim Rejections – 35 U.S.C. § 102

29. Previous rejection of Claims 69 and 70 under 35 U.S.C. § 102(b) as being anticipated by Cooper *et al.* is withdrawn by virtue of Applicants' cancellation of said claims.

30. Previous rejection of Claims 69, 70, and 77 under 35 U.S.C. § 102(b) as being anticipated by Cooper *et al.* as evidenced by Gershenwald *et al.* is withdrawn by virtue of Applicants' cancellation of said claims.

Maintained – Claim Rejections – 35 U.S.C. § 102

31. Previous rejection of Claims 20, 71 and 74-76 under 35 U.S.C. § 102(b) as being anticipated by Cooper *et al.* is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that Cooper *et al.* do not teach the lid region as defined by the amended Claim 20. Firstly, as noted above, the lid region is unclear and, broadly but reasonably interpreted is included in the lipase polypeptide taught by Cooper *et al.* Moreover, without definition of the term "variant" in Claims 74-76, the lipase polypeptide of Cooper *et al.* still meet the limitations of these claims.

32. Previous rejection of Claims 78-84 and 95 under 35 U.S.C. § 102(b) as being anticipated by Cooper *et al.* as evidenced by Gershenwald *et al.* is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that no fragment is taught by Cooper *et al.* This is not convincing because no definite structure is found in Claim 85. Thus, the lipase polypeptide of Cooper *et al.* can reasonably be considered to be a "fragment" (as little as minus one amino acid) of a polypeptide meeting the limitation of

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Claim 85. Moreover, the common sequence assures antigenicity. Additionally, the Examiner notes that no comments concerning particularly the rejection of Claims 78-84 herein are recited by Applicants. For these reasons, the instant rejection is maintained.

NEW OBJECTIONS/REJECTIONS

Claim Objections

33. Claims 74-76 are objected to for depending from canceled Claim 72. The instant claims will be examined herein as if they depend from Claim 20.

34. Claims 96 and 97 are objected to as duplicate claims. While the claims vary their dependence, their further limitations are identical rendering their scope identical. One of these two claims must be cancelled.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35. Claims 20, 71, 74-76, and 78-84 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a 39 kD catalytic domain of the triacylglycerol lipase family" is unclear. As noted above, the metes and bounds of the domain are ill defined in the specification. Appropriate clarification is required.

Summary of Issues

36. The following is a summary of issued pending in the instant Application that require Applicants' attention:

- a) Claims 1, 7, 8, 10, 11, 13-16, 19, 21-23, 40-41, 43-47, 49-53, 55-59, 63-65, 73, 93, and 94 are drawn to non-elected inventions and must be cancelled in response to a Final Office action.
- b) The drawings are considered informal and must be corrected in response.
- c) The specification stands objected to for being confusing about the origin of the LIPG protein sequences.
- d) The Abstract stands objected to for not completely describing the disclosed subject matter.
- e) Claims 74-76 stand objected to for depending from canceled Claim 72.
- f) Claim 95 stands objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.
- g) Claims 96 and 97 stand objected to as duplicate claims.
- h) Claims 20, 71, 74-76, 78-88, and 95 stand rejected under 35 U.S.C. § 112, second paragraph for the abbreviation "LIPG".
- i) Claims 20, 71, 74-76, and 78-85, 87, 88 and 95 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "a 39 kD catalytic domain of the triacylglycerol lipase family".
- j) Claims 90 and 91 stand rejected under 35 U.S.C. § 112, second paragraph, as being unclear as to how a polypeptide having the same amino acid sequence (SEQ ID NO:8) can produce different bands (68 kD and 55 kD) on a 10% SDS-PAGE gel.
- k) Claims 20, 71, 74-76, 78-85, 87, 88, and 95 stand under 35 U.S.C. § 112, first paragraph, written description.
- l) Claims 20, 71 and 74-76 stand under 35 U.S.C. § 102(b) as being anticipated by Cooper *et al.*
- m) Claims 78-84 and 95 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Cooper *et al.* as evidenced by Gershenwald *et al.*

Conclusion

37. Claims 96 and 97 are objected to; Claims 20, 71, 74-76, 78-91, and 95 are rejected. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



PONNATHAPUACHITTA MURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER

KMK
February 5, 2003